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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

EXAMINER	
MCKELVEY, T	
ART UNIT	**PAPER NUMBER**
1636	7

DATE MAILED: 12/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/396,539	Applicant(s) Palese et al.
	Examiner Terry A. McKelvey	Group Art Unit 1636

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *35-44* _____ is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *35-44* _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. §§ 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821(d). The application refers to sequences without the use of the correct identifier.

For example, at page 22, line 14, page 104, line 18, and throughout the entire application, including Figure 2, etc, sequences have been set forth without sequence identifiers.

Also, there is no statement filed in the application indicating that the CRF disk and the paper sequence listing are the same and include no new matter.

Applicants should carefully review the specification to identify and properly label each sequence that is referred to within the specification, including drawings. Sequences in drawings can be identified with a SEQ ID NO: in the Brief Description of the Drawings for the figure or be present in the figure itself. If one or more sequences are referred to in the specification that are not present in the Sequence Listing, then a new Sequence Listing, a new CRF diskette containing the Sequence Listing and a new statement that the two are the same

and includes no new matter must be submitted in order to fully comply with the Sequence Rules.

Applicants are required to comply with all of the requirements of 37 C.F.R. §§ 1.821 through 1.825. *Any* response to this Office Action which fails to meet *all* of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. §§ 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

Priority

If applicant desires priority under 35 U.S.C. § 120 based upon a parent application, specific reference to the parent application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. Status of the parent application (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "Patent No." should follow the filing date of the parent application. If a parent application has become

abandoned, the expression "abandoned" should follow the filing date of the parent application.

In the instant case, reference has been made to the immediate parent, 09/106,377, but not to the applications that '377 claims priority to, such as 08/252,508, 07/527,237, and others. It appears that the applicant intended to claim priority to those applications because the applications are set forth in the instantly filed oath/declaration and in the Remarks filed 11/10/99, the applicant points to support for the instant claims to '237. Amending the first paragraph of the instant specification to include this continuity data (the applications set forth in the oath/declaration) would be remedial. The instant application has been examined based upon the priority as claimed in the oath/declaration.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because:

The filing date given for application S.N. 07/440,053 (November 24, 1989) is incorrect. The correct filing date is November 21, 1989.

Claim Objections

The numbering of claims is not accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 36-45 have been renumbered to claims 35-44.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 35, the use of "polymerase of a negative strand RNA virus" renders the claim vague and indefinite because the preamble reads "... chimeric negative strand RNA virus" and thus it is unclear whether "RNA virus" is an intended limitation or not. It appears to be an intended limitation from the specification and thus addition of "RNA" between "strand" and "virus" would be remedial. Also, there is no positive antecedent basis for "the polymerase proteins" and "the chimeric virus".

Regarding claims 37, 41, and 44, the use of "rescued" renders the claim vague and indefinite because it is unclear in what way a virus can be rescued when the method results in a virus being recovered. Amending the claim to replace "rescued" with "recovered" would be remedial.

Regarding claim 38, there is no positive antecedent basis for "the RNA polymerase proteins" and "the chimeric virus".

Regarding claim 39 and 40, the use of "influenza" renders the claim vague and indefinite because "influenza" is a disease, not a virus as implied by the use of the term. Amending the claim to insert "virus" after "influenza" would be remedial.

Regarding claim 42, the use of "encloding" renders the claim vague and indefinite because of the apparent misspelling of "encoding". The use of "negative strand virus" renders the claim

vague and indefinite because it is unclear whether "an influenza virus" is meant instead because the resulting virus is a chimeric influenza virus (and thus only reverse complements of an mRNA coding sequence for an RNA-directed RNA polymerase of an influenza virus could produce what the preamble states, a chimeric influenza virus). Also, there is no positive antecedent basis for "the polymerase proteins" and "the chimeric virus".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 37, 41, and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-26 of U.S. Patent No. 5,166,057. Although the conflicting claims are not identical, they are not

patentably distinct from each other because of the following reasons.

The claims of '057 are drawn to a chimeric negative strand RNA virus comprising a heterologous sequence comprising the reverse complement of an mRNA coding sequence operatively linked to a polymerase binding site of a negative strand RNA virus. The instant claims are drawn to chimeric viruses which due to the method steps used to create them, are the same as the '057 chimeric viruses except that they are broader in scope (e.g., a limitation such as the reverse complement is not present) while totally encompassing the '057 chimeric viruses. Thus, the instant claims, if allowed, would extend patent protection of the '057 chimeric viruses in addition to providing patent protection to chimeric viruses not encompassed by the claims of '057. Also, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the '057 patent, then two different assignees would hold a patent to the claimed chimeric viruses of '057, and thus improperly there would be possible harassment by multiple assignees.

Claims 37, 41, and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-25 of U.S. Patent No. 5,854,037.

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims of '037 are drawn to a chimeric influenza virus comprising a heterologous sequence comprising the reverse complement of a bicistronic mRNA coding sequence operatively linked to a polymerase binding site of a influenza virus. The instant claims are drawn to chimeric viruses which due to the method steps used to create them, are the same as the '057 chimeric viruses except that they are broader in scope (e.g., a limitation such as the reverse complement of a bicistronic mRNA coding sequence is not present) while totally encompassing the '037 chimeric viruses. Thus, the instant claims, if allowed, would extend patent protection of the '037 chimeric viruses in addition to providing patent protection to chimeric viruses not encompassed by the claims of '037. Also, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the '037 patent, then two different assignees would hold a patent to the claimed chimeric viruses of '037, and thus improperly there would be possible harassment by multiple assignees.

Claims 37, 41, and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,001,634. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims of '634 are drawn to a chimeric influenza virus comprising a heterologous sequence from another strain of influenza virus comprising the reverse complement of an mRNA coding sequence operatively linked to a polymerase binding site of a negative strand RNA virus. The instant claims are drawn to chimeric viruses which due to the method steps used to create them, are the same as the '634 chimeric viruses except that they are broader in scope (e.g., a limitation such as the reverse complement is not present) while totally encompassing the '634 chimeric viruses. Thus, the instant claims, if allowed, would extend patent protection of the '634 chimeric viruses in addition to providing patent protection to chimeric viruses not encompassed by the claims of '634. Also, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the '634 patent, then two different assignees would hold a patent to the claimed chimeric

viruses of '634, and thus improperly there would be possible harassment by multiple assignees.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 6:30 AM to about 5:00 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Richard Schwartz, can be reached on (703) 308-1133.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

December 17, 2000

09/396,539
search keywords
for paper no. 7

negative (w) strand?

virus or viruses

chimeric or recombinant

RNA (w) polymerase?

influenza (w) vir?

heterologous

genomic

segment?